

Division of Dockets Management 5630 Fishers Lane Room 1061 Rockville, MD 20852

RE: Docket No 2004N-0456; Advanced Notice of Proposed Rulemaking; Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes.

The Grocery Manufacturers Association¹ (GMA) appreciates this opportunity to offer comments concerning the Food and Drug Administration's (FDA) advanced notice of proposed rulemaking on serving sizes of products that can reasonably be consumed at one eating occasion; updating of reference amounts customarily consumed (RACC) and approaches for recommending smaller portion sizes.

General Comments

GMA supports changes to the Nutrition Facts Panel (NFP) to help consumers better understand serving size if consumer research shows that these changes would increase readability and consumer understanding. GMA strongly encourages the agency to implement changes related to serving size in conjunction with changes related to Dietary Reference Intakes (DRIs) and accelerate the DRI revision process. By accelerating the DRI process in this way, FDA would bring in the next generation of NFP labeling changes in a timely manner and at the same time diminish costly packaging changes incurred by food manufacturers. GMA recognizes the magnitude of this endeavor, but as with NLEA changes a decade ago, there is great value in introducing NFP label changes all at one time to consumers. This would eliminate the need to educate consumers on two "waves" of labeling changes, as well as make the label changes more efficient and economical for industry. Accordingly, FDA should adopt an accelerated schedule for both calorie/serving size-related changes and DRI changes to maximize the positive public health impact for consumers.

20044.0456

C 60

¹ The Grocery Manufacturers of America (GMA) represents more than 140 brand name food, beverage and consumer products companies. Since 1908, GMA has been an advocate for its members on public policy issues and has championed initiatives to increase industrywide productivity and growth. The association, which is led by a board of member company chief executives, represents an industry with annual U.S. sales of \$500 billion and 2.5 million employees in all 50 states. For more information, visit the GMA Web site at www.gmabrands.com.

GMA took the opportunity within this ANPR to be creative and think outside the box to provide suggestions to the agency on changes to the format of the NFP to more closely tie the Serving Size and the Calories to the nutrition information. GMA believes this improvement would dramatically increase visual attention to the importance of Serving Size. A description of the NFP is provided in Appendices A and B.

GMA believes that the serving size for food and beverage products should be based on federal nutrition policy as reflected in the Dietary Guidelines and MyPyramid, not on the increasing amounts of food that people are now eating. The ultimate goal is for Americans to learn that the serving size in the NFP provides guidance for healthy eating practices. This approach would address the concerns of the Obesity Working Group.

A. Updating RACCs

Throughout the revisions of the HHS/USDA Dietary Guidelines and the USDA Food Guide Pyramid, GMA called upon government to harmonize educational information across all consumer touch points: Dietary Guidelines, Food Guidance System and the NFP. GMA called on government to base the number of servings on a 2,000 calorie diet to align with the NFP. GMA was pleased to see the government incorporate this recommendation into the Dietary Guidelines and MyPyramid (see GMA comments at: http://www.gmabrands.com/news/docs/listcomments.cfm).

GMA also recommended harmonizing serving size within the Food Guidance System and the NFP. Consumers have expressed confusion over the serving sizes needed to achieve food recommendations. However, MyPyramid does not provide serving sizes but rather total daily recommended amounts of foods within the six food groups, for twelve different individualized MyPyramids. To help remedy potential consumer confusion, GMA suggests that for those foods or beverages included in the MyPyramid, that manufacturers may link the existing RACCs to MyPyramid within the NFP. This may be accomplished by use of dietary guidance statements for each MyPyramid food group on packages.

Specifically, GMA encourages the agency to retain the footnote describing the basis of the Percent Daily values and the fact that an individual's Daily Values may vary, and expand on it as follows:

- For foods included in MyPyramid, the NFP could have an additional footnote prior to the current footnote:
 - * For a 2,000 calorie diet, you've consumed 1 cup of the suggested 3 cup equivalents from the Dairy group. For more personalized nutrition information go to www.MyPyramid.gov.
 - ** Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

- For foods not included in MyPyramid or for products not using the additional voluntary footnote (above), add to the current footnote a statement informing consumers that more detailed information is available at MyPyramid:
 - * Percent Daily Values are based on a 2,000 calorie diet. Your Daily values may be higher or lower depending on your calorie needs. For more personalized nutrition information go to www.MyPyramid.gov

As noted above, as well as in our comments on FDA's companion rulemaking on Prominence of Calories, GMA supports this linkage on the food label. FDA's "Calories Count" report, on which these ANPRs were based, were issued well in advance of the Dietary Guidelines and MyPyramid, and FDA could not have reasonably anticipated how to allow such linkage in the ANPRs. However, now that the Dietary Guidelines and MyPyramid have been issued, it is imperative that FDA allow linking the NFP with those landmark documents. It has been suggested that the Dietary Guidelines, MyPyramid and the Nutrition Facts Panel form a "three legged stool" of nutrition policy. To ensure that stool is strong and in proper balance, GMA strongly recommends that FDA allow voluntary linkage between the RACCs and MyPyramid, as described above.

GMA opposes any requirement that the current NFP be revised to reflect serving sizes actually consumed that are different from current federal dietary recommendations, whether larger or, especially, smaller, such as for milk and vegetables. Common sense argues against using larger serving sizes on the food label. Adoption of larger "official" serving sizes would require that responsible nutrition and dietary advice inform consumers to eat, for example, two-thirds or one-half of the labeled serving size, simply leading to more confused consumers or, worse, more consumers ignoring the NFP completely.

An increase in the RACC on food labels would thus only exacerbate the current obesity problem. RACCs should reflect sound nutrition principles, not a diet that inexorably leads to over-consumption of food and thus obesity and attendant health problems. A review of federal law more specifically supports this position.

First, Congress explicitly included "education" as a key component of the Nutrition Labeling and Education Act (NLEA) of 1990. It would be inconsistent with the educational purpose of the NLEA to use serving sizes that promote obesity. Even though consumers in many cases eat the amount of food they want, serving size information should foster sound dietary patterns that maximize personal health, not over-consumption that leads to obesity and disease.

Second, the National Nutritional Monitoring and Related Research Act of 1990 -- enacted by Congress in the same year as the NLEA -- explicitly requires that FDA, along with USDA, establish Dietary Guidelines for Americans every five years that reflect sound nutrition and dietary habits. The provisions of 21 U.S.C. 5341(a)(2) require that these Guidelines "be based on the preponderance

of the scientific and medical knowledge." Emphasizing larger serving sizes that contribute to obesity would directly conflict with this statutory mandate.

Third, Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits labeling that is false or misleading in any particular. Use of larger serving sizes in the NFP would mislead consumers into believing that these serving sizes represent healthful dietary patterns, thus directly violating the statutory prohibition.

Fourth, nothing in the NLEA requires FDA to incorporate as part of nutrition labeling larger serving sizes that represent unhealthy dietary choices. Section 403(q)(1)(A)(i) of the FD&C Act states only that the serving size used in the NFP is to be "an amount customarily consumed." The statute does not state that an amount customarily consumed must be based on national food consumption patterns. The statute does not state by whom the amount is customarily consumed. Faced with a similar issue two years ago (in interpreting the prohibition against false or misleading labeling), FDA determined that it is appropriate to use a "reasonable person" standard. Thus, FDA is not compelled by this statutory requirement to use larger serving sizes that can contribute to serious health problems and disease. The flexibility inherent in the "customarily consumed" terminology provides FDA with ample authority to maintain current serving sizes without change. Indeed, the entire purpose of NLEA would be thwarted by implementing serving sizes that lead consumers to unhealthful eating patterns.

If FDA requires Percent Daily Value (%DV) for calories then the serving size must reflect the recommended amount to consume and not a disproportionately large serving size. Otherwise, the % DV for calories would be based on an amount of food that does not reflect a recommended amount, and the NFP (rather than serving as an educational tool) would only perpetuate confusion among consumers regarding proper consumption levels. FDA has the golden opportunity to leverage the serving size as a tool to educate consumers on the recommended amount of food to consume.

B. Single Serving Containers

GMA recognizes the need to better communicate calorie information on single serving packages. Over the years since NLEA, packaging has evolved to meet consumers' changing lifestyles.

One of GMA's member companies conducted consumer research with over 1500 individuals to determine the best approach to labeling snacks and beverages that provide several RACC servings in a package that could possibly be consumed in a single eating occasion. They found that large segments of the population *do not usually* consume the product as a single serving. Instead, *usually* the product is shared or some is saved. The GMA member company found that RACC information is clearly relevant for many consumers, especially women and children.

GMA supports the flexibility for food companies to provide nutrition information for single serving packages in a variety of ways such as a dual column format or adding an extra line to provide calories per container information (Appendix C). Example A is in no way intended to discount or eliminate current flexible options allowed today. GMA and its members feel that manufacturers should **not** be required to provide nutrition information on **an entire package basis only** because that would give consumers "permission," or even "encouragement," to eat the entire package. The NFP is to provide factual nutrition information about the product and should be used as an educational tool to promote healthy eating behaviors among Americans. The NFP also should reflect federal dietary recommendations on the amount consumers should eat.

GMA supports the flexibility to include the number of servings/package on the Principal Display Panel (PDP) on single serving packages if a manufacturer chooses, rather than a mandatory regulation. Allowing a voluntary link of the RACC and MyPyramid could further reinforce the message of how much they are consuming, including single serving packages.

During the development of NLEA, FDA did not believe that it should require the number of servings on the front panel of products that contain more than the upper limit for the single-serving container. The agency was concerned that such a requirement would result in an information overload and contribute to the space problem for single-serving containers. GMA believes that reasoning still holds true today.

Appendix D provides examples of food and beverage products currently in the marketplace that provide number of servings/package on the PDP.

C. Comparison of Calories in Foods of Different Portion Sizes

GMA member companies provide a broad range of package sizes within a single brand to meet consumer demands. GMA believes that having smaller package sizes available to consumers may be helpful in managing their intake of food, and may also be more economical for individuals who consume smaller amounts of food.

Other Issues Regarding the NFP Format

GMA encourages FDA to examine changing graphics in the NFP to more closely tie the Serving Size and Calories together. This change would dramatically increase visual attention to the importance of Serving Size. The current NFP requires manufacturers to put a 7 point rule line between the Serving Size information and the nutrition information. An unintended consequence of the current NFP format design is the uncoupling of Calories from the Serving Size. Today, many consumers do look at the nutrition information but they do not always link it to the Serving Size. In addition, bolding and increased font size of serving information may increase consumer attention to the importance of serving size. However, FDA needs to conduct consumer research on any potential changes to the serving size declaration or other aspects of the NFP format to

evaluate whether such enhancements will meaningfully impact consumer choices and dietary behavior.

The NFP has been in existence for over 10 years and consumers easily recognize and look for this label icon. Accordingly, there is no longer a need to dictate, in the regulations, the placement of the NFP on the food label. Thus, we recommend that it be allowed to be placed anywhere on the label and not only on the Information Panel (IP). Currently, the agency says that it may be placed elsewhere only if there is insufficient space on the IP, but GMA suggests it may be placed anywhere and still be easily identified by consumers.

GMA suggests the FDA eliminate the upper limit of 40 square inches of available label space for alternative nutrition labeling formats. Currently, labels that have 40 square inches or less of space available for labeling may modify the NFP requirements² by using a tabular display, eliminating the footnote, using abbreviations and placing the panel anywhere on the label rather than on the currently designated IP.³ GMA believes this flexibility should be available to all labels.

GMA looks forward to working with the agency on this very important issue in the months ahead.

> Sincerely yours, in Kretser

Alison Kretser, MS, RD

² 21 CFR 101.9 (j) (13) (ii). ³ 21 CFR 101.1 (a).

APPENDIX A

Example (Multiple Serving Container)

Shifted "Servings Per Container" and "Calories Per Container" to the right to separate container information from serving size information

2 Point Line Rule

"Servings Per Container", "Calories Per Container", "Serving Size", and "Calories" bolded and 10 point font size

Moved Serving Size and Calories together

Footnote linking to MyPyramid.gov

Nutrition Facts

Servings Per Container 14

Serving Size 1 cup (32 g)) [*]	
Amount Per Serving Calories 120	%Daily Value**	
Total Fat 1.5 g	2%	
Saturated Fat 0g	0%	
Trans Fat 0 g		
Cholesterol 0mg	0%	
Sodium 200 mg	8%	
Total Carbohydrate 24g	8%	
Dietary Fiber 4 g	15%	
Sugars 5 g		
Protein 5 g		
Vitamin A 0% •	Vitamin C 8%	
Calcium <2% •	Iron 4%	

*For a 2,000 calorie diet, you've consumed 1 ozequivalent (oz-eq) of the suggested 6.5 oz-eq from the Grains group. Make half your grains whole. For more personalized nutrition information go to www.MyPyramid.gov.

**Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

APPENDIX B

Example A

Current Label

Serving Size 1 cup (228g) Servings Per Container 2 Amount Per Serving Calories 260 Calories from Fat 120 % Daily Value" Total Fat 13g 20% 25% Salurated Fat 5c Trans Fat 2g 10% Cholesterol 30mg Sedlum 660mg 28% **Total Carbohydrate 31g** 10% Dietary Fiber 0g Sugars 5g Protein 5g Vilamin C 2% Vitamin A 4% Calcium 15% Iron 4% Percent Daily Values are based on a 2,000 calorie dist Your Daily Values may be higher or lower depending on your calcife needs: 2,000 2,500 Total Fat 800 **M**O Sal Fat 25g 300mg Cholesteral Less than 300mg Sodium 2,400mg 2,400mg Total Carbohydrate 300a 3750 Dielary Fiber Calories per gram: Fat 9 Carbohydrate 4 Protein 4

Example B

NFP for Multiple Serving Container

Nutrition Facts

Servings Per Container 14

Amount Per Serving Calories 120	%Daily Value*	
Total Fat 1.5 g	2%	
Saturated Fat 0g	0%	
Trans Fat 0 g		
Cholesterol Omg	0%	
Sodium 200 mg	8%	
Total Carbohydrate 24g	8%	
Dietary Fiber 4 g	15%	
Sugars 5 g		
Protein 5 g		
Vitamin A 0% •	Vitamin C 8%	
Calcium <2% *	Iron 4%	

*For a 2,000 calorle dlet, you've consumed 1 ozequivalent (oz-eq) of the suggested 6.5 oz-eq from the Grains group. Make half your grains whole. For more personalized nutrition information go to www.MyPyramid.gov.

**Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

Example A

NFP for Single Serving Container

Nutrition Facts

Servings Per Container 2 Calories Per Container 400

Serving Size 1 cup	(240 mL)*
Amount Per Serving Calories 200	%Daily Value**
Total Fat 5 g	8%
Saturated Fat 3g	15%
Trans Fat 0 g	
Cholesterol 15mg	6%
Sodium 150 mg	6%
Total Carbohydrate 32g	11%
Dietary Fiber <1g	3%
Sugars 30 g	
Protein 8 g	
Vitamin A 10% •	Vitamin C 2%
Calcium 40% •	Iron 2%

^{&#}x27;For a 2,000 calorie diet, you've consumed 1 cup of the suggested 3 cup equivalents from the Dairy group. For more personalized nutrition information go to www.MyPyramid.gov.

Example B

NFP for Single Serving Container Dual Column format

Nutrition Serving Size 8 ft Servings Per Cor	oz (240) dalner s	mL) bout 2
Amount Per Suring	Ha	1 belils
Caliries	110	230
^	K Daily	Value ***
Total Fat Og*	PX.	DAY.
Sødium 20mg	1%	2%
Total Carb. 30g	10%	20%
gntare and		
Protein Ug	· · · · · · · · · · · · · · · · · · ·	/
" Amount is 8 ff co. 1 before Scaleure, 60g Total Darkoby Og Protein		
*** Proort Delytshes on tes	eden 12/00	cabie list

^{**}Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

APPENDIX D

Parent Company	Information on the Principal Display Panel
	Products that Label Servings of Snack Packages
Kraft Foods	Nabisco Go-Paks: "About 4 Servings"
Land O' Lakes	Snack n' Cheese to Go: 10 3/4 oz portions
	Products that Label Serving Size on Frozen Foods/Meals
Campbell's	Supper Bakes: Makes 6 Servings
ConAgra	Banquet Crock Pot Classics: Serves 5
General Mills	Betty Crocker Meals: Most "Helpers" list number of servings per package
General Mills	Green Giant Create a Meal: 3 Servings
General Mills	Nature Valley Bars: all bars state the number of bars in the carton
General Mills	Pillsbury Toaster Strudel: 6 Toaster Pastries
Gorton's Seafood	Gorton's Grilled Fillets: 2 Fish Fillets
Nestle	Stouffers Skillets: Serves 2
Unilever	Bertolli Complete Skillets: Serves 2
	Products that Label Serving Pasta & Side Dishes
Barilla America, Inc.	Barilla Tortelloni: Serves 2-3
General Mills	Betty Crocker Scalloped Potatoes: 2 1/2 servings
Kraft Foods	StoveTop Stuffing: Makes 6 1/2 Cup Servings
	Products that Label Serving Size on Beverages
Coca-Cola Company	Hi-C: 10 Pouches
Kraft Foods	Kool-Aid Jammers: 10 Pouches
	Other Products that Label Serving Size
PepsiCo, Inc.	Quaker Instant Oatmeal: 10 Packs